

**REMARKS**

**I. STATUS OF THE CLAIMS**

Claims 16-40 are pending. No claim amendments have been made.

**II. INFORMATION DISCLOSURE STATEMENT**

Applicant filed an Information Disclosure Statement with PTO-Form 1449 on February 18, 2000. The Examiner has indicated that no Information Disclosure Statement is in the Patent Office file. On April 4, 2002, Applicant provided the Examiner with an additional copy of the Information Disclosure Statement, PTO-Form 1449, and references cited therein as originally filed on February 18, 2000. As further evidence that such documents were actually filed on February 18, 2000, Applicant also provided on April 4, 2002, the date-stamped postcard listing the above items. Applicant respectfully requests the Examiner to consider the references filed on February 18, 2000, and to initial and return to the undersigned the PTO-Form 1449. Also, Applicant notes that the Examiner's statements about the "Information Disclosure Statement filed on May 7, 2001," not complying with 37 C.F.R. §1.97(c) are irrelevant because Applicant did not file an Information Disclosure Statement on May 7, 2001. What was submitted was merely a copy of the PTO-1449 already filed on February 18, 2000.

**III. REJECTION UNDER 35 U.S.C. §103(a)**

In the Final Office Action, the Examiner rejected claims 16-40 under 35 U.S.C. §103(a) over WO 97/49378 (Terranova). Applicant traverses the rejection for the reasons already of record as well as those presented below.

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To establish a *prima facie* case of obviousness, three basic criteria must be met. The prior art reference must teach or suggest all the claim elements. There must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify reference teachings. Finally, there must be a reasonable expectation of success in making the proposed modification. M.P.E.P. § 2143 (8<sup>th</sup> ed. 2001).

**A. The Examiner Has Shown No Motivation To Modify Terranova**

In the present case, the Examiner has failed to show any suggestion or motivation to modify Terranova with a reasonable expectation of success. As a result, no *prima facie* case of obviousness has been made.

**1. *The Examiner Relied on General Teachings of Optional Additives as the Basis for Motivation***

Terranova teaches an oxidation dyeing composition comprising at least one specific pyrazolo[1,5-a]pyrimidine derivative as an oxidation base. Terranova further teaches that his composition can optionally also contain at least one additional oxidation base (chosen from a long list set forth at page 9, lines 24 to page 11, line 6) and at least one coupler (chosen from a list as set forth at page 11, lines 12-30). The Examiner appeared to be relying on these general teachings of optional additive dye ingredients as the basis for the requisite motivation to select Applicant's specifically claimed second base, *i.e.*, N,N-bis( $\beta$ -hydroxyethyl)-paraphenylenediamine, and specifically claimed coupler classes, *i.e.*, meta-phenylenediamines and meta-aminophenols of formula (II), for use in Terranova's composition.

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More specifically, the Examiner contended that "Terranova teaches that the compositions may also contain a coupler in the claimed amounts in order to modify the shades or enrich the glints, wherein preferred couplers include both m-aminophenols and m-phenylenediamines as claimed." (Office Action dated December 7, 2000, at 3, and Office Action dated July 12, 2001, at 3.) The Examiner also contended that "Terranova teaches that it is known and conventional in the hair dyeing art to mix oxidation bases and couplers in order to obtain a wide variety of colors." (Office Action dated December 7, 2000, at 4, and Office Action dated July 12, 2001, at 4.) These two statements appear to underpin the Examiner's position that it would have been obvious to add the claimed "second oxidation base to Terranova's exemplified compositions and processes . . . , resulting in compositions and processes as claimed, because the patentee teaches that this claimed additional oxidation base may be added to the patentee's compositions, and . . . that it is known and conventional in the hair dyeing art to mix different oxidation bases and couplers in order to obtain a wide variety of colors." (Office Action dated December 7, 2000, at 3-4, and Office Action dated July 12, 2001, at 4.)

2. *Combinations of Bases and Couplers are Known to Form Dyes, but This Knowledge Alone is Insufficient to Render Obvious Specific Combinations as Claimed*

Applicant maintains that the Examiner has not shown the requisite motivation to obtain the presently claimed invention from Terranova's disclosure. First, although it is well known that many different combinations of oxidation base(s) and coupler(s) can form oxidation dyes, this knowledge would not in itself have motivated one of ordinary skill in the art to select two particular oxidation bases and one particular coupler, such

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as the presently claimed components, for use in an oxidation dye composition.

Similarly, although the list of approved oxidation bases and couplers which are safe and useful for dyeing hair is generally known to one of ordinary skill in the art, (see, e.g., G. Wis-Surel, "Some Challenges in Modern Hair Colour Formulations," *International Journal of Cosmetic Science*, 21, (1999) p. 329-330) there is no reason why this knowledge of known, useful oxidation bases and couplers would have motivated one of ordinary skill in the art to select the two particular oxidation bases and one particular coupler, such as the presently claimed components, for use in an oxidation dye composition.

Specifically, because many oxidation bases and couplers are already known, and because it takes time to determine which are safe for use, an invention in the oxidation dye art may often involve, instead of brand new dye components, combinations of known oxidation bases and couplers to achieve a certain color or whatever properties the inventor is trying to obtain. Practically speaking, to be marketable, an oxidation hair dye must meet certain requirements, such as, *inter alia*, resistance of the coloration to external factors such as light, washing, permanent waving, perspiration, or rubbing. See specification at p.2; see generally, e.g., J. Corbett, "An Historical Review of the Use of Dye Precursors in the Formulation of Commercial Oxidation Hair Dyes," *Dyes and Pigments*, vol. 41 (1999), p. 135. Further, a combination of an oxidation base and coupler may be selected for color, as suggested by the Examiner in the present case, or the combination may be selected to improve stability, rheological properties, diffusion of the dye into the hair, rinseability, inclusion of effective conditioning agents, viscosity, or rapid dyeing effect. See, e.g., U.S. Patent No. 5,393,305 to Cohen at col. 1, lines 34-

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60. Thus, because the formulation of an oxidation dye requires consideration of so many different criteria, one of ordinary skill in the art would need more than the general guidance of Terranova, *i.e.*, that additional bases and couplers can optionally be added, to be motivated to make the necessary selections to arrive at the presently claimed invention.

For at least this reason, the Examiner's contention that one of ordinary skill in the art would have been motivated to select the presently claimed components because it is known that oxidation bases and couplers are combined to modify shades of color, is insufficient to provide a *prima facie* case of obviousness

3. *Colors are Based not only on Bases and Couplers Used but also on Other Variables Involved in the Oxidation Dyeing Process*

Although it is known that color is obtained from oxidation bases or a mixture of oxidation bases and couplers, varying shades of color can be achieved by the selection of certain other variables that are part of the process of oxidation dyeing. Thus, while it is true that couplers may be used to modify the shade or color of an oxidation dye composition comprising an oxidation base, couplers are not the only means for modifying the shade or color of an oxidation dye composition.

As an initial matter, when discussing color, it is important to clarify whether the color at issue is the color of the oxidation dye composition in solution (how it looks in the bottle) or the color of the dyed hair because the physical properties of hair affect the resultant color of a dye on the hair. This is why people with different hair types and different original hair color will obtain varying results in terms of dyed hair color even when using the same oxidation dye composition.

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Several other variables also affect the color (both in solution and in the hair), including the number of oxidation bases and couplers used, the types of oxidation bases and couplers used, the pH of the aqueous solution, and the make-up of the hair fiber itself. As discussed in detail below, a change in any of these factors would necessarily modify the shade or glint of the aqueous dye solution or of the dyed hair.

As stated by one skilled artisan:

The final colour produced is a function of the amounts and nature of the individual primary intermediates [i.e., oxidation bases] and couplers in the composition and the pH at which the process is performed. . . . While the chemical reaction involved in colour formulation from a mixture of primary intermediates and couplers in solution are well understood, the stage has not been reached where this knowledge can be used to formulate shades in the absolute sense.

J. Corbett, "Hair Colorants: Chemistry and Toxicology," *Cosmetic Science Monographs*, Number 2, Micelle Press, Weymouth, Dorset, England, (1998) pp. 21.

**(a) Background: The Oxidation Dyeing Process**

Oxidation dyeing is a chemical reaction wherein a colorless compound called an oxidation base (also known as a "primary intermediate" or an "oxidation dye precursor") is oxidized to a reactive intermediate compound. The process is complicated, but the gist is that, via oxidation condensation/polymerization, the reactive intermediate reacts, either with itself or with a coupler compound, to form a colored dye inside the hair fiber. See *The Science of Hair Care*, Charles Zviak, ed., Marcel Dekker, Inc. New York (1986) pp. 268-269. ; See also S. Pohl, Ph.D., "The Chemistry of Hair Dyes," *Cosmetics & Toiletries*, vol. 103, (1988) p. 62. The role of the hair itself in the dyeing process is discussed further below.

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**(b) Choice of Oxidation Base(s) and Coupler(s)**

The color of the oxidation dyeing solution (*i.e.*, the color in the "bottle," not on the hair) can often be predicted based upon the use of certain combinations of one known oxidation base and one known coupler. This is because the reaction schemes of various combinations of a single oxidation base and a single coupler are known. See, *e.g.*, Zviak at pp 280-284. For example, the reaction scheme of p-phenylenediamine with a separate coupler is known. See, *e.g.*, K. Brown, "Hair Colorants," *J. Soc. Cosmet. Chem.*, vol. 33, (1982), p. 377. However, once the equation is changed, and other ingredients are added to the one known oxidation base and the one known coupler, then it is harder to predict the color in solution. "[A]ny varying element can cause a major change." Zviak at p. 272. For example, listed below are three of the many ways to vary the oxidation base-coupler reaction scheme such that the resulting color becomes difficult or impossible to predict:

(1) If a new (previously unknown) oxidation base or new coupler is used, then it is not possible to predict the color of the oxidation dyeing solution because the reaction scheme is not known.

(2) If additional oxidation base(s) or coupler(s) are added to the composition, as in the presently claimed composition, which comprises at least two oxidation bases and at least one coupler (a minimum of three ingredients), then the reaction scheme becomes much more complicated and the color of the resultant solution becomes much more difficult to predict. Note, for instance, that the extensive chart in the Zviak book, cited above, covers only binary mixtures.

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(3) Finally, every species in a given genus of couplers does not necessarily provide the same color, in solution or in hair, when reacted with the same oxidation base because the different species of couplers will have different substituents which will react differently with the oxidation base, thereby resulting in a different reaction scheme.

**(c) Variations in pH**

As mentioned above, pH may effect the color of the oxidation dye composition in solution or in the hair. As stated by G. Wis-Surel:

There are also other composition aspects that impact colour performance of the final product. For example, pH of the colouring mixture has a pronounced effect on the final colour developed in hair. ... Reaction rate of colour formation is affected by pH of the medium whereby the colour intensity and, in some cases, colour hue is changed. ... The same shade can be produced by several different dye compositions, but one dye composition can also produce different shades depending on pH and other parameters of the delivery vehicle.

G. Wis-Surel at pp. 327 and 330. For example, the effect of pH on color formation in hair using one oxidation base and one coupler is shown in the following table.

pH	resorcinol + p-phenylenediamine	pH	p-aminophenol
6.6	dark brown	5.9	warm red brown
8.5	med. slightly redder brown	8.6	light warm red brown
10	med. slightly yellow greenish brown	9.9	light yellow blond

*Id.* at 332. As can be seen from the data in the table, adjusting the pH from alkaline to neutral to acidic can provide a wide range of colors even using the same oxidation dye composition. See also J. Corbett, "Chemistry of Hair Colorant Processes - Science as an aid to Formulation and Development," *J. Soc. Cosmet. Chem.*, 35, (1984) pp. 297-



310. Accordingly, even knowledge of the colors expected from known oxidation base and coupler combinations is not enough to allow one of ordinary skill in the art to predict the color of a combination where pH varies.

**(d) Physical Properties of the Hair Itself**

As noted above, due to the physical properties of hair, including the fact that there are a variety of hair types and colors, it is difficult to predict hair color after an oxidation dye composition has been used. Pohl describes the problems associated with oxidation dyeing of human hair:

[T]he outer part of the human hair or cuticle, is made up of a number of layers of interlocking scales. If it is desired that the color not rub off the hair or be easily rinsed from the hair, then the molecules of dye must penetrate the cuticle and be adsorbed in the cortex....[H]uman hair must be dyed near room temperature, with a relatively short application time. Therefore, in order to penetrate the cuticle of human hair, molecules need to diffuse very readily. This means that the molecules that comprise hair dyes must be small ones. However, in order to be intensely colored enough to be usable as a dye, a molecule needs a considerable amount of conjugation. Therefore, in order to be a dye, a molecule must be relatively large.

Pohl, at p. 58. However, because the dye molecules are large, a major percentage of the dye is formed outside of the hair fiber and gets washed out of the hair during the rinsing process. A minor percentage of the dye is formed inside the hair and because the dye molecules are large, the dye does not easily diffuse out of the hair, thereby creating a permanent dye. *Id.* at 62

A further complication in predicting the color of dyed hair is that different hair types have different rates of diffusion. As stated by J. Corbett in "Chemistry of Hair Colorant Processes - Science as an aid to Formulation and Development" at p. 299:

A further complication in predicting the outcome of competing reactions inside the hair fiber is that it will depend not only on the relative reactivity of the competing couplers, but also on their relative rates of diffusion from the dye bath into the hair. Furthermore, for competing reactions taking place inside a swollen keratin fiber, we do not know to what extent the rate of the coupling reactions will be diffusion controlled.

Pohl further supports Applicant's position with his conclusion that:

Since a number of competing chemical reactions are going on simultaneously to effect the final color result, it may be imagined that making natural-appearing shades of oxidation dyes products is very complicated. The actual chemistry is even further complicated: the hair plays a part in the final result, in that the diffusion of the intermediates into the [h]air, both before and after any chemical reactions have occurred, plays an important part of the process, and one cannot predict the final color result from a knowledge of the solution chemistry of the dyes.

Pohl, at p. 64 (emphasis added).

Thus, as stated by those skilled in and familiar with the art, namely, the authors of the various technical articles cited above, the color resulting from a specific combination of at least three oxidation dye components, as presently claimed, cannot be predicted. Further, there is no guidance in Terranova, based on all the many factors that must be considered in preparing a hair dye, to choose Applicant's particular ingredients with the expectation of achieving the resistant, unselective oxidation dye composition presently claimed. As the Examiner knows, obviousness requires at least some degree of predictability (*see* M.P.E.P. § 2143.02 (8<sup>th</sup> ed. 2001)), and here it is not possible to predict the color or the resultant properties of the oxidation dye composition.

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4. *The Examiner Argued No Motivation to Modify is Required Because all Claim Elements are Taught by Terranova*

In response to Applicant's arguments of record that no motivation to modify Terranova exists, the Examiner argued that because "the reference teaches all of the claim limitations, there is no need for motivation to modify the reference." (Office Action dated July 12, 2001, at 5). Specifically, she argued that "[t]here is no motivation needed since Terranova specifically teaches adding an additional oxidation base ... [A]dditionally it is notoriously well known to use combinations of oxidation bases in oxidative hair dyeing." (Office Action dated July 12, 2001, at 6). Applicant respectfully submits that regardless of whether the claim elements are all present in Terranova or not, a *prima facie* case of obviousness also requires that the reference provides the motivation to make the claimed invention. M.P.E.P. §2143 (8<sup>TH</sup> ed. 2001). Here, Terranova teaches known oxidation bases and known couplers and that it is known in the art to combine these components to create an oxidation dye composition. However, for the many reasons set forth above, the reference does not provide the motivation to pick and choose amongst all the known oxidation bases and couplers to select the three specifically claimed components for use in an oxidation dye composition.

**B. The Examiner Improperly Relied on *In re Kerkhoven***

Finally, the Examiner argued that "[i]t is *prima facie* obvious to combine two compositions each taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose" (Office Action dated July 12, 2001, at 6) (citing *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980)). Even though Applicant is unsure which two "compositions" the Examiner had in mind Applicant submits that reliance on *Kerkhoven* to establish a *prima facie* case of

obviousness here is improper, because the holding and reasoning of *Kerkhoven* do not apply to this case. In *Kerkhoven*, the applicant claimed a process for preparing a detergent composition comprising mixing two known detergent materials. The court reasoned that "the idea of combining [the two detergent materials] flows logically from their having been individually taught [each for the very same purpose, *i.e.*, as detergents] in the prior art." 205 U.S.P.Q. 1069, 1072. Based on this reasoning, the court held that the claims at issue requiring "*no more than the mixing together*" of two conventional detergents to make a third detergent composition set forth "prima facie obvious subject matter." *Id.* (emphasis added).

The present invention, however, does not fall within the facts of *Kerkhoven* for several reasons. First, the present invention does not involve merely mixing two dyeing compositions. The presently claimed composition is a combination of three ingredients, and not two, as discussed by *Kerkhoven*. Further, although they are used for the same overall purpose of dyeing hair, an oxidation base and a coupler actually have different roles, in that the oxidation base is indeed the required "base" for an oxidation dye color whereas the coupler is only a color modifier, and cannot generally be used on its own as a dye like the base can. Thus, the oxidation bases and coupler of the presently claimed composition are not separate compositions as *Kerkhoven* uses the term, but instead components of a single composition, each with its own role in the composition.

Second, as discussed at length above, the Examiner in the present case is picking and choosing these ingredients from different parts of the reference, and from long lists of possible compounds, in an attempt to obtain the presently claimed invention. One of ordinary skill in the art, unless relying on hindsight, would not have

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had any reason or guidance to make these very specific selections. This picking and choosing hardly qualifies as "mere mixing."

Third, while *Kerkhoven* involved the mere mixture of two detergents, the oxidation dye composition of the present invention involves an oxidation reaction, as discussed at length above; again, hardly a "mere mixture." See, e.g., *Zviak* at pp. 263-286.

For at least the foregoing reasons, the Examiner has failed to establish a *prima facie* case of obviousness. Applicant requests reconsideration and withdrawal of the rejection.

#### IV. CONCLUSION

In view of the foregoing remarks, Applicant respectfully requests the reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: August 9, 2002

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